REMARKS

Claims 1-22 were pending in the present application. Claims 8-11, 13-17 and 19-22 have been canceled without prejudice and claims 1, 2 and 12 have been amended. Therefore, claims 1-7, 12 and 18 will be pending upon entry of the present amendment. No new matter has been added.

Claim Objections

Claims 1-7, 12 and 18 are objected to because they recite non-elected sequences. Applicants have amended claims 1, 2 and 12 to remove reference to any non-elected sequences, thereby rendering the Examiner's objection moot. Reconsideration and withdrawal of the objection is respectfully requested.

Rejection of Claims 1-7, 12 and 18 Under 35 U.S.C. § 112, ¶2

Claims 1-7, 12 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner states that "The term "stringent conditions" in claim 1 (and its dependent claims 2-7 and 18), and claim 12 is unclear. Applicants respectfully traverse the rejection, however in order to expedite prosecution, Applicants have amended claims 1 and 12 to remove reference to the term "stringent conditions", thereby rendering the rejection moot over claims 1-7, 12 and 18. Therefore, Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 112, second paragraph rejection over claims 1-7, 12 and 18.

Rejection of Claims 1-7, 12 and 18 Under 35 U.S.C. § 112, ¶2

Claims 1-7, 12 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner states that "The term "naturally occurring allelic variant" in claim 1 (and its dependent claims 2-7 and 18), and claim 12 is unclear. Applicants respectfully traverse the rejection, however in order to expedite prosecution, Applicants have amended claims

1 and 12 to remove reference to the term "naturally occurring allelic variant", thereby rendering the rejection moot over claims 1-7, 12 and 18. Therefore, Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 112, second paragraph rejection over claims 1-7, 12 and 18.

Rejection of Claims 1-7, 12 and 18 Under 35 U.S.C. § 112, ¶1

Claims 1-7, 12 and 18 are rejected under 35 U.S.C. § 112, first paragraph, because "[t]he specification, while being enabling for isolated DNA sequences encoding SEQ ID NO:5, does not reasonably provide enablement for any of the following:

i) isolated DNA molecules comprising DNA sequences which are at least 85% identical to SEQ ID NO:4 and 6 with no function,

ii) isolated DNA molecules comprising a fragment of at least 300 nucleotides of SEQ ID NO:4 and 6 with no function,

iii) isolated DNA molecules comprising a fragment of at least 15 contiguous amino acids of SEQ ID NO:5 with no function, and

iv) isolated DNA molecules encoding a naturally occurring allelic variant of SEQ ID NO:5, wherein the nucleic acid molecules hybridize to SEQ ID NO:4 or 6 or complements thereof, under stringent conditions, with no function."

Applicants respectfully traverse this rejection, however in the interest of expediting prosecution, and in no way acquiescing to the Examiner's rejection, Applicants have amended claims 1 and 12 to remove reference to fragments and allelic variants of the polypeptide. Applicants have additionally amended claims 1 and 12 to read "a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:4 or SEQ ID NO:6, wherein the nucleic acid encodes a polypeptide having kinase activity".

The limitations within newly pending claims 1 and 12 are fully enabled within the specification as Applicants have provided teachings for every element needed for one of skill in the art to practice the claimed invention.

First, Applicants have provided which regions of the 12599 sequence can be altered and

still encode a polypeptide encompassed by the claims. Specifically, Applicants have taught several domains and regions within the 12599 polypeptide which are conserved and essential for activity of the polypeptide, namely the i) protein kinase catalytic domain; ii) the protein kinase ATP-binding region; iii) the serine/threonine kinase active site signature sequence; iv) the tyrosine protein kinase active site; and v) the pleckstrin homology domain (refer to, for example, paragraphs [0031], [0036]-[0037], [0039] and [0041]-[0042] on pages 7-9). By having identified the regions necessary for activity, Applicants have taught which regions of the polypeptide are amenable to alterations as well as those which are not amenable to alterations.

Second, the specification teaches one how to generate functional variants by performing conservative substitutions within the polypeptide used in the claimed invention. As defined on page 18, a "conservative amino acid substitution" is one in which the amino acid residue is replaced with an amino acid residue having a similar side chain." The Applicants have also defined which of the amino acids have similar side chains, thereby providing a skilled artisan the necessary tools to generate functional variants of the polypeptide used in the claimed invention.

Finally, Applicants have provided teachings for one of skill in the art to be able to perform assays to determine whether or not specific sequences have the desired kinase activity. As taught on, for example, page 34 of the specification, paragraph [0128], assays performed in cells expressing the 12599 molecule of the present invention, or variants thereof, can be performed where one would monitor 1) intracellular calcium, IP3 or diacylglycerol concentration; 2) phosphorylation profile of intracellular proteins; or 3) the activity of an 12599-reguated transcription factor. By monitoring these activities, one can perform assays to determine whether or not a variant having at least 95% identity to the molecule of the present invention has the desired properties. Applicants submit that performing such assays would not constitute undue experimentation.

Therefore, Applicants have provided all of the necessary information to enable one of skill in the art to 1) identify regions within the molecule of the present invention which may be altered while maintaining kinase activity; 2) generate variants having at least 95% identity to the molecule of the present invention; and 3) perform assays to determine whether or not the sequences generated do in fact have the desired kinase activity.

Therefore, contrary to the Examiner's assertions, Applicants have provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of newly pending claims 1-7, 12, and 18. Applicants therefore respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 112, first paragraph rejection over claims 1-7, 12 and 18.

Rejection of Claims 1-7, 12 and 18 Under 35 U.S.C. § 112, ¶1

Claims 1-7, 12 and 18 are rejected under 35 U.S.C. § 112, first paragraph "[a]s failing to comply with the written description requirement." Specifically, the Examiner states "Claims 1 (and its dependent claims 3-7) and 12 are directed to a **genera** of DNA sequences that are not adequately described in the specification."

Applicants respectfully traverse this rejection, however in the interest of expediting prosecution, and in no way acquiescing to the Examiner's rejection, Applicants have amended claims 1 and 12 to remove reference to fragments and allelic variants of the polypeptide. Applicants have additionally amended claims 1 and 12 to read "a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:4 or SEQ ID NO:6, wherein the nucleic acid encodes a polypeptide having kinase activity".

"The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed'" *See Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000). In particular, an adequate description can be made by disclosing identifying characteristics, such as complete or partial structure, functional characteristics, or physical and/or chemical properties. "Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, first paragraph 'Written Description' Requirement," 66 Fed. Reg. 1099 (January 5, 2001). An Applicant may also rely upon functional characteristics in the description, provided there is a correlation between the function and structure of the claimed invention. *Id.*

Newly pending claim 1 recites an isolated nucleic acid molecule comprising a nucleotide

sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:4 or SEQ ID NO:6, wherein the nucleic acid encodes a polypeptide having kinase activity. Newly pending claim 12 recites a method of producing a polypeptide comprising the amino acid sequence of SEQ ID NO:5, wherein the polypeptide is encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:4 or SEQ ID NO:6, wherein the polypeptide has kinase activity.

The recitation of at least 95% sequence identity is a *very predictable structure* of the sequences encompassed by the claimed invention. The Examiner is reminded that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. 66 Fed. Reg. 1099, 1106 (2001). Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. 66 Fed. Reg. 1099, 1106 (2001). Applicants submit that the knowledge and level of skill in the art would allow a person of ordinary skill to envision the claimed invention, *i.e.*, an isolated nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:4 or SEQ ID NO:6, wherein the nucleic acid encodes a polypeptide having kinase activity.

Furthermore, the description of a claimed genus can be by structure, formula, chemical name, or physical properties. *See Ex parte Maizel*, 27 USPQ2d 1662, 1669 (B.P.A.I. 1992), *citing Amgen v. Chugai*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). A genus of DNAs may therefore be described by means of a recitation of a representative number of DNAs, defined by nucleotide sequence, falling within the scope of the genus, or by means of a recitation of structural features common to the genus, which features constitutes a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); see also Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, first paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (2001). The recitation of a predictable structure of at least 95% sequence identity to SEQ ID NO:4 or 6 is sufficient to satisfy the written description requirement.

As indicated above, an applicant may also rely upon functional characteristics in the description, provided there is a correlation between the function and structure of the claimed invention. The claimed methods recites wherein the polypeptide has kinase activity, thus the claims provide a functional characterization of the sequences claimed in the genus.

Example 14 of the Revised Interim Written Description Guidelines is directed to a generic claim: a protein having at least 95% sequence identity to the sequence of SEQ ID NO:3, wherein the sequence catalyzes the reaction A to B. The Training Materials concludes that the generic claim of Example 14 is sufficiently described under 35 U.S.C. §112, first paragraph, because 1) "the single sequence disclosed in SEQ ID NO:3 is representative of the genus" and 2) the claim recites a limitation requiring the compound to catalyze the reaction from A to B. The Guidelines conclude that one of skill in the art would recognize the necessary attributes possessed by the members of the genus.

Following the analysis of Example 14, Applicants submit that newly pending claims 1 and 12, and dependent claims 2-7 and 18 therefrom, satisfy the written description requirements of 35 U.S.C. §112, first paragraph. Specifically, the claims of the present invention encompass an isolated nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:4 or SEQ ID NO:6, wherein the nucleic acid encodes a polypeptide having kinase activit; and a method of producing a polypeptide comprising the amino acid sequence of SEQ ID NO:5, wherein the polypeptide is encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:4 or SEQ ID NO:6, wherein the polypeptide has kinase activity. As in Example 14, the specification discloses the amino acid sequence of SEQ ID NO:5, and the claims recite a limitation requiring the compound to have a specific function (*i.e.*, kinase activity).

In summary, the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Applicants submit that the relevant identifying physical and chemical properties of the disclosed genus would be clearly recognized by one of skill in the art and consequently, the Applicant has disclosed the necessary common attributes or features of the

elements possessed by the members of the genus. Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 112, first paragraph rejection over claims 1-7, 12 and 18.

Rejection of Claims 1, 3-7, 12 and 18 Under 35 U.S.C. § 102(e)

Claims 1, 3-7, 12 and 18 are rejected under 35 U.S.C. § 102(e) as being anticipated by Wei et al. (U.S. Patent No. 6,482,624). Specifically, the Examiner states that "Wei teaches a DNA sequence (see its SEQ ID NO:1) that encodes a polypeptide comprising at least 15 contiguous amino acids of SEQ ID NO:5."

Applicants respectfully traverse the rejection, however in order to expedite prosecution, Applicants have amended claims 1 and 12 to remove reference to fragments, thereby rendering the rejection moot over claims 1, 3-7, 12 and 18. Therefore, Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 102(e) rejection over claims 1, 3-7, 12 and 18.

Rejection of Claims 1, 3-7, 12 and 18 Under 35 U.S.C. § 102(e)

Claims 1, 3-7, 12 and 18 are rejected under 35 U.S.C. § 102(e) as being anticipated by Zeng et al. (US20030108533). Specifically, the Examiner states that "Zeng teaches about a DNA sequence (see its SEQ ID NO:5) that encodes a polypeptide comprising at least 15 contiguous amino acids of SEQ ID NO:5 of this invention."

Applicants respectfully traverse the rejection, however in order to expedite prosecution, Applicants have amended claims 1 and 12 to remove reference to fragments, thereby rendering the rejection moot over claims 1, 3-7, 12 and 18. Therefore, Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 102(e) rejection over claims 1, 3-7, 12 and 18.

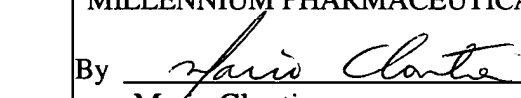
CONCLUSION

In view of the amendments and remarks made herein, Applicants respectfully submit that the objections and rejections presented by the Examiner are now overcome and that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is believed that this paper is being filed timely and that a one month extension of time is required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

February 17, 2005	MILLENNIUM PHARMACEUTICALS, INC. By  Mario Cloutier Limited Recognition Under 37 C.F.R. §11.9(b) 40 Lansdowne Street Cambridge, MA 02139 Telephone – (617) 577-3522 Facsimile – (617) 551-8820